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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF DARREN R. HURST, M.D.**

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Darren R. Hurst, M.D. ("Motion" or "Mot.") [Doc. 7302]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and Daubert ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., (collectively "Bard") now seek to preclude Darren Hurst, MD ("Dr. Hurst") from testifying: (1) that Bard filters have higher complication rates than other manufacturer's filters, including an unacceptable rate of caudal migration; (2) that Bard ignored safety signals and elected not to perform studies to evaluate durability, safety and efficacy while at the same time representing its filters as having superior safety, quality and performance; and (3) that

Bard should have communicated to doctors that Bard's Meridian should have been used instead of its Eclipse filter. Motion at 2.

Dr. Hurst's first two opinions at issue concern the ability of a physician to perform an accurate and complete risk-benefit analysis when deciding whether to prescribe a filter and, if so, which filter should be used, and to obtain proper informed consent from his or her patient. The information provided (or not provided as in this case) to physicians by a medical device company, such as complication rates, design concerns and safety problems, has a direct bearing on the ability of physicians to perform these crucial functions.

Bard misstates the third opinion as it pertains to Ms. Jones and Ms. Hyde. Dr. Hurst's reports for those plaintiffs do not state that Bard failed to communicate to doctors that Bard's Meridian filter should have been used instead of its Eclipse filter. Rather, Dr. Hurst opines, *inter alia*, that prior to those plaintiffs being implanted with their filters Bard was aware of significantly increased risks of caudal migration with the G2/G2X/Eclipse, had internally deemed that caudal migration risk unacceptable, and had initiated an internal project to correct the caudal migration problem in February 2006 - more than four years before Ms. Jones received her Eclipse filter and five years before Ms. Hyde was implanted with a G2X filter. Dr. Hurst further opines that Bard should have stopped selling those filters and removed them from the market. Hurst Expert Reports on Jones and Hyde, Def. Exs. F and G. So the parties are in agreement that Bard could not have offered its Meridian filter to Ms. Jones' or Ms. Hyde's implanting physician for sale, but it certainly could have taken action to prevent them from receiving filters it knew were improperly designed and posed an unacceptable risk. Thus, with regard to the Jones and Hyde cases, Dr. Hurst is not even offering the opinion Bard's instant motion seeks to preclude.

Dr. Hurst does offer the third opinion at issue in Ms. Mulkey's case, and he is more than qualified to offer this opinion as well as the opinions discussed above. Dr. Hurst is fellowship trained and board-certified in vascular and interventional radiology, has been

practicing medicine full time for more than 20 years, and has personal experience with the use of both permanent and retrievable inferior vena cava ("IVC") filters for the prevention of pulmonary embolism. Hurst CV, Exhibit 1; *see also* Def. Exs. A, F and G, Dr. Hurst's Rule 26 expert reports as to Debra Mulkey, Doris Jones and Lisa Hyde). Dr. Hurst regularly implants and retrieves IVC filters, and is familiar with the relevant medical literature concerning IVC filter indications and contraindications for use, placement, and complications and risks and benefits of the devices, among other issues. Def. Exs. A, F, and G. Dr. Hurst has authored several articles published in peer-reviewed journals, including being lead author on articles published in the Journal of Vascular Surgery and Journal of Vascular and Interventional Radiology. Ex. 1. Dr. Hurst is and has been a Lead Investigator for several studies conducted at the St. Elizabeth Health System. *Id.*

In formulating his opinions, Dr. Hurst reviewed 24 Bard documents, deposition transcripts of 19 Bard witnesses and more than 50 peer-reviewed publications. *See e.g.* Def. Ex. A appendix. This is far superior to the materials reviewed by Bard's experts, as Bard decided *not to provide any* internal documents or Bard employee/former employee depositions to those experts – choosing instead to have them provide opinions without knowing the full story. In addition to these documents, Dr. Hurst relied on his vast clinical experience with IVC filters, including Bard IVC filters, in combination with his education and training in the field of medicine, and specifically, the field of Vascular and Interventional Radiology. Def. Exs. A, F and G; Exhibit 2, August 7, 2017 Hurst Dep. at 245:25–246:24.

Simply put, Bard is wrong and its motion should be denied in full.

II. ARGUMENT

A. Applicable Legal Standard/*Daubert*

Plaintiffs direct the Court to Plaintiffs' Omnibus Memorandum, which they expressly incorporate herein.

B. Dr. Hurst Is Eminently Qualified to Opine Regarding Information Doctors Need and Want from a Medical Device Manufacturer in Order to Perform a Risk-Benefit Analysis and Obtain Complete and Proper Informed Consent from their Patients.

In order to practice "standard of care medicine", physicians require sufficient information to conduct a well-informed risk-benefit analysis of whether to prescribe an IVC filter and, if so, which specific filter to use, as well as to provide accurate and complete information to their patients in order to obtain informed consent. As explained by Dr. Hurst at his deposition, in order to conduct a risk-benefit analysis and disclose all relevant medical information to patients, he expects "a medical device manufacturer to provide [him] information that's going to help [him] make [his] decisions." Ex. 2 at 49:12-19. This is not a foreign concept to Bard, as its expert witnesses and employees agree with Dr. Hurst:

- Bard's regulatory affairs expert, Dr. Donna-Bea Tillman, testified: "I think that physicians need to have enough information to understand the risks and the benefits in order to advise their patients… [a]nd to provide informed consent." Exhibit 3, August 4, 2017 Tillman Dep. at 292:1-14;
- Bard's former Vice President of Research and Development, Len DeCant, agreed Bard has an obligation to disclose to doctors all information relating to its product in order to make determinations regarding whether to use the device. Exhibit 4, May 24, 2016 DeCant Dep. at 304:10-24;
- Bard's Vice President of Science and Technology, John DeFord, agreed that the risk/benefit has to be evaluated with every device and that doctors need to be aware of the risk of any device prior to recommending that device to a patient. Exhibit 5, June 2, 2016 DeFord Dep. at 130:20 – 131:8; and
- Bard's former Vice President of Regulatory Sciences and Head of Quality Assurance, Christopher Ganser, testified: "It's true I want the doctors to have as much information as possible to make an informed decision how to

use the product." Exhibit 6, October 11, 2016 Ganser Dep. at 208:2 – 209:7.

With regard to conducting a risk benefit analysis, Dr. Hurst testified that it is his job to evaluate the clinical situation, weigh the risk and benefits to the patient and then explain those risks and benefits to the patient so the patient can make an informed decision. Ex. 2 at 36:15-37:7. Dr. Hurst's report discusses the AMA Code of Medical Ethics and ethics opinions pertaining to informed consent and his adoption of the AMA Codes in his daily practice. *See e.g.* Def. Ex. A, pp.8-9. Dr. Hurst cites the AMA Code of Medical Ethics' Opinion 8.08 mandating that physicians "disclose all relevant medical information to patients." *Id.* at p. 9.

It is within this risk-benefit analysis/informed consent framework that Dr. Hurst opines, based on his experience, Bard's own internal documents and the medical literature, that Bard filters have higher complication rates than other filters, including an unacceptable caudal migration rate as determined by Bard, and that Bard ignored safety risks and issues choosing instead to falsely represent the safety and efficacy of their filters in their marketing materials. Dr. Hurst opines that these actions impaired the ability of physicians like him to weigh the risks and benefits of using Bard filters and to provide/obtain informed consent to patients (such as plaintiffs) on the use of Bard filters.

1. <u>Dr. Hurst Is Qualified to Access Reported Complication Rates in the Peer-Reviewed Literature and Bard's Internal Analyses and Draw Conclusions Regarding Whether a Particular Rate, Including the Rate of Caudal Migration, Is Acceptable to an Implanting Physician.</u>

Dr. Hurst testified his opinion that Bard filters have higher complication rates is based "on the available medical literature, based on personal experience, based on discussions with other physicians in [his] region and area, attendance at national meetings and discussions that were ongoing at the time as well, and then also review of internal documents from Bard discussing health hazard evaluations, discussing MAUDE data." Ex. 2 at 52:12-24. Dr. Hurst also relies on the *Deso* study, a meta-analysis published in the peer-reviewed literature that shows across many studies that Bard filters have higher

complication rates than competitor filters. Ex. 2 at 263:1 – 265:9. In addition to reviewing the *Deso* article, Dr. Hurst testified that he also reviewed articles included in the *Deso* meta-analysis. Ex. 2 at 267:14 – 268:2. Dr. Hurst explains that he principally relies on the *Deso* article because the authors found 1,472 articles and included in their analysis "English language clinical trials involving humans from 1980 to 2014." Ex. 2 at 269:1–270:3. Moreover, with regard to his opinions about complication rates, Dr. Hurst found further support in Bard's internal documents. Ex. 2 at 265:11-15.

Bard's argument that Dr. Hurst is unqualified to offer these opinions based on his review of the medical literature regarding complication rates because he is not a biostatistician or epidemiologist is not supported by the law. The first question under Rule 702 is whether the expert is qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. As another Judge of this Court has written, "Rule 702 'contemplates a broad conception of expert qualifications... [and] is broadly phrased and intended to embrace more than a narrow definition of qualified expert.'" *Ericson v. City of Phoenix*, No. CV-14-01942-PHX-JAT, 2016 WL 6522805, at *3 (D. Ariz. Nov. 3, 2016) (quoting *Thomas v. Newton Int'l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)). In discussing the Ninth Circuit standard for qualifications, the *Thomas* court wrote that Federal Rule of Evidence 702 requires only a "minimal foundation" to be qualified to give expert testimony. *Thomas*, 42 F.3d at 1269-70; *see also Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004). Further, "the advisory committee notes emphasize that Rule 702 is broadly phrased and intended to embrace more than a narrow definition of qualified expert." *Id.* at 1269. "Any one or more of the bases given" in Rule 702 "is sufficient to qualify a witness as an expert." *Heighley v. J.C. Penney Life Ins. Co.*, 257 F. Supp. 2d 1241, 1254 (C.D. Cal. 2003) (citing 4 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence*, § 702.04 [1][c] (Joseph M. McLaughlin, ed., Matthew Bender 2d ed. 2002)).

In *Ericson*, this Court assessed the credentials of a nurse practitioner to opine about the effects of an officer's carotid hold on the decedent's death. *Ericson*, 2016 WL

6522805, at *4. The defendant argued that she was unqualified to offer that opinion because she was "not an emergency room doctor, forensic medical examiner, forensic pathologist, toxicologist, biomechanical or human factors expert, or police officer." *Id.* But the Court allowed the opinion, stating that the nurse's "knowledge and experience related to strangulation and its effects are extensive." *Id.* The argument Bard makes here is nearly identical and should be denied.

Nor is there any support for Bard's argument that Dr. Hurst is required to verify the information in the *Deso* article, analyze what may have been missing and independently assess potential biases. "That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science." *See Daubert II*, 43 F.3d at 1318 (citing *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786 ("[S]crutiny of the scientific community is a component of 'good science[.]'")). As such, Bard's motion to exclude Dr. Hurst's testimony regarding higher complication rates, including unacceptable caudal migration rates, should be denied.

2. Dr. Hurst Is Qualified to Opine Regarding the Safety Risks and Issues Ignored by Bard and the False Representations in Bard's Marketing Materials.

Dr. Hurst succinctly explains his role as a physician and implanter of medical devices as one of liaison between medical device manufacturer and the patient.

> Because I'm serving as the intermediary for the patient between the medical device company and the patient. It's my duty, my job, to evaluate the situation, the clinical situation, and the devices to make sure that I provide the correct management for the patient. Most patients don't have the medical knowledge to completely evaluate an IFU and weigh their own risk and benefits. It's my job to try to explain to them my interpretation of the risks and benefits so that they can make an informed decision.

Ex. 2 at 36:21–37:7. He is also unequivocal that he relies on the medical device manufacturer to provide him with the information he requires to make treatment decisions

for his patients, and that if he does not have accurate and/or sufficient information from a medical device manufacturer regarding safety and risk he is unable to do his job. Ex. 2 at 49:2-19.

It is as a treating physician who has implanted and retrieved IVC filters, served as an intermediary between the IVC manufacturers and patients, and conducted risk-benefit analyses that Dr. Hurst reviewed Bard documents and provided his opinion that Bard ignored safety risks, failed to disclose relevant safety risks, failed to evaluate durability, safety and efficacy, and falsely represented superior safety, quality and performance. Given his clinical experience, Dr. Hurst is well positioned to evaluate these issues and provide these opinions.

Bard's argument that Dr. Hurst's opinions are outside his areas of expertise is meritless. He does not provide any opinions regarding the design or manufacture of the filters or the testing of the filters. To the extent he provides opinions regarding marketing, they are limited to the representations made in Bard's IVC filter marketing materials distributed by Bard to physicians. Given that he is part of the target audience for these materials and regularly receives them, it is within his expertise to testify regarding the accuracy of the representations made in these materials versus what Bard knew when it provided those materials to physicians. Ex. 2 at 16:3-12 (establishing that he implanted Bard filters through 2012); 68:17-25 (stating his opinions regarding marketing are based on marketing materials he received and his personal experience with Bard's sales personnel).

Bard also argues that Dr. Hurst relies on a relatively small number of representative documents from Bard's production to support his opinions. This argument is specious. In litigation, each party selects a subset of material documents produced in discovery to use (otherwise, trials would last years and jurors would be overwhelmed with mountains of unhelpful exhibits). Many of the documents to be used as exhibits at trial in this product liability litigation involve complex technical and scientific information and thus require expertise to define and explain those exhibits. The Ninth Circuit has recognized

"the importance of expert testimony when an issue appears to be within the parameters of a layperson's commonsense, but in actuality, is beyond their knowledge." *U.S. v. Finley*, 301 F.3d 1000 (9th Cir. 2002); *see also Pooshs v. Philip Morris, USA, Inc.*, 287 F.R.D. 543, 553 (N.D. Ca. 2012) ("To the extent that the documents discuss complex scientific theories, and that information is within [the plaintiffs' epidemiologist's] area of expertise, the court would permit the testimony.").

Moreover, during his deposition Bard had the opportunity to present Dr. Hurst with internal documents it believes refute the Bard documents Dr. Hurst relied on, but chose not to do so.[1] Bard will also have this opportunity at trial during cross-examination to the extent any such contradictory documents exist. For these reasons, Bard's motion to preclude Dr. Hurst from offering these opinions should be denied.

C. Dr. Hurst is Qualified to State that Bard Did Nothing to Communicate to Physicians That the Meridian Should Be Used Instead of the Eclipse Before Ms. Mulkey Was Implanted with an Eclipse Filter.[2]

The fact that Dr. Hurst was no longer implanting Bard filters at the time the Meridian filter was released does not negate his opinion that Bard should have informed doctors to use the Meridian filter instead of its G2, G2X, or Eclipse filters that, according to Bard, incorporate safety features not present in its older filters. Nor does it make him unqualified to give this opinion. Dr. Hurst's knowledge of the safety problems with these earlier filters coupled with his understanding of what an implanting physician would want to know to keep patients as safe as possible more than qualify him to provide this opinion.

Bard incorrectly argues that based on the record evidence Dr. Hurst does not know what information Bard shared with physicians who implanted Bard filters. Dr. Hurst

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[1] In fact, Bard also chose to keep its own experts in the dark and not allow them to see any internal documents.

[2] As referenced earlier in this opposition brief, Dr. Hurst never gave this opinion with regard to Plaintiffs Jones and Hyde because the Meridian filter was not yet on the market. As such, there is no response that can be given, and Bard's Motion on this issue is moot. That being said, Dr. Hurst does plan to give, and is not conceding, his opinion that the filters implanted in Jones and Hyde should have been pulled from the market prior to implant taking place.

testified that he used Bard filters up until around time the Meridian came on the market, which was in or around September 2011. Ex. 2 at 102:18-21. He also testified that his opinions are based on marketing materials he received and his interaction with Bard sales personnel. Ex. 2 at 68:17-25. Under these circumstances, Dr. Hurst is more than qualified to testify with regard to what Bard was and was not telling physicians. More tellingly, Bard failed to put forth a shred of evidence to support its argument. It did not attach a single document showing that it communicated to physicians that they should use the new and allegedly improved Meridian filter instead of the G2 or Eclipse, which did not have caudal anchors. Nor did Bard cite to any deposition testimony despite nearly 50 depositions of its employees, including more than 15 sales representatives, to support its argument. Under these circumstances, Bard's motion to exclude this testimony should be denied.

D. Dr. Hurst's Testimony Regarding Issues Underlying Risk-Benefit Analysis and Informed Consent Will Assist the Trier of Fact.

Informed consent and the information physicians require to provide/obtain informed consent from patients are not "lay matters." These issues, which involve the judgment of a medical doctor, are clearly beyond the knowledge of average jurors and require expert testimony. *See Scharf v. Trabucco*, 2017 WL 105993, *5 (D. Ariz. Jan. 11, 2017) (quoting *Evans v. Bernhard*, 533 P.2d 721, 724 (Ariz. Ct. App. 1975) ("The medical standard of care must be established by expert medical testimony unless the conduct complained of is readily ascertainable by a layman"). Arizona courts have "[left] the precise parameters of the required disclosure for any particular informed consent case to be established by expert testimony in accordance with the applicable standard of care." *Saccuci v. U.S.*, 2009 WL 1531842, *19 (D. Ariz. June 2, 2009) (quoting *Duncan v. Scottsdale Med. Imaging Ltd.*, 70 P.3d 435, 438-39 (2003)).

The Ninth Circuit has also permitted expert witnesses to provide narratives and factual summaries of corporate documents by expert witnesses that help the jury understand complex issues and a lot of background information in similar litigation.

Staub v. Breg, Inc., No. CV 10–02038–PHX–FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) (allowing the plaintiffs' regulatory expert in medical device litigation to testify at trial despite objections that her report was a narrative as long as expert provided "some analysis, opinion, or expertise when testifying" and noting that narrative testimony objections were "best made at trial"); *Johnson v. Wyeth LLC*, No. CV 10–02690–PHX–FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) (same); *United States v. Newmont USA Ltd.*, No. CV-05-020-JLQ, 2007 WL 4856859, at *3 (E.D. Wash. Nov. 16, 2007) (holding that fact that expert's opinion was "based upon a narrative of facts based upon his own review of documentary evidence already in the record" did not render expert's testimony inadmissible). Nor has "Narrative" ever been a proper basis for excluding a witness or their opinions under Rule 702 or *Daubert*. "The objection that testimony is 'narrative' is an objection to form, foundation or responsiveness, and must be presented at trial . . . ." *In re Actos (Pioglitazone) Products Liab. Litig*., No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014); *see also In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, MDL No. 2100, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) (holding that objections to Dr. Kessler's expert testimony on the grounds that his "factual narratives and summaries of Bayer documents are not the proper subject of expert testimony" should be decided in context of trial).

Dr. Hurst's testimony is necessary to assist the trier of fact to understand the evidence and to determine facts at issue here, such as what information should have been disclosed to implanting physicians. Bard's Motion to exclude this testimony should be denied.

III. CONCLUSION

Based on the foregoing, Bard's motion should be denied.

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti